MAY - 4 2001

K003943

Appendix 2

510(k) Summary of Safety and Effectiveness

Company: Linde Medical Sensors AG

Address: Linde Medical Sensors AG
Austrasse 25
4051 Basel - Switzerland

Telephone: 011 41 61 278 82 07
Telefax: 011 41 61 278 81 81

Contact Person: Jean-Pierre Palma (Regulatory Affairs)

Date: May 3, 2001

Proprietary Name: MicroGas 7650 Transcutaneous Monitor

Common Name: Cutaneous Gas Monitor

Classification Name: Monitor Carbon Dioxide Cutaneous (73LKD) / Monitor Oxygen Cutaneous for Infant not under anesthesia (73KLK).

Equivalent Device: The modified MicroGas 7650 is substantially equivalent to the MicroGas 7650 approved under 510(k) K991644.

Intended Use:

The Linde Transcutaneous Monitor is intended to measure the partial pressure of oxygen and carbon dioxide that passes through the cutaneous layer of the skin of an infant who is not under gas anesthesia, by a sensor attached to the surface of the infant's skin.
The intended use of the modified device as described in its labeling, has not changed as a result of the modifications.

Description of the Device:

1) General Description:

Detailed description of the device is contained in the MicroGas 7650 Operator's Manual located in Appendix 8 of this document.

2) Description of the modifications:

a) Software changes:
New calibration algorithm

b) Hardware changes:
New microprocessor (another type of the same family but with a larger size of on-chip RAM) and minor layout change on main board

c) Labeling changes:
Operator's manual changes reflecting the software changes mentioned above (as described in appendix 1) and minor service manual changes reflecting the hardware changes mentioned above

Non-Clinical Tests of Equivalency:

- The intended use of the modified device has not changed as a result of the modifications.

- The fundamental scientific technology of the device has not been altered.
The device's operating principles or mechanism of action have not been changed. The operating principle of the Combi.M Sensor and the microprocessor based monitor have not been modified. The operating principle of the calibration has also not been modified: it is still a one gas fully automatic calibration. Only the algorithm used for the detection of the stabilisation of the PCO2 values during the calibration has been improved in order to reduce the calibration time and the Cal Gas consumption.

- The accuracy of the new calibration algorithm has been verified by comparative In vitro and In Vivo tests performed in house. The results demonstrate that the new calibration algorithm is equivalent to the previous one (see validation reports 7650.00.805-10, 7650.00.805-11 and 7650.00.805-40).

Conclusion of the non-clinical tests:

The non-clinical tests performed demonstrate that the modifications do not affect the safety and effectiveness of the device.

Patrick Eberhard
R&D Manager
May 3, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Mr. Jean-Pierre Palma
Linde Medical Sensors AG
Austrasse 25
4051 Basel - Switzerland

Re: K003943
MicroGas 7650 Transcutaneous Monitor
Regulatory Class: II (two)
Product Code: 73 KLK, LKD
Dated: April 2, 2001
Received: April 5, 2001

Dear Mr. Palma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 6

510(k) Number (if known): ~~K992871~~ K003943

Device Name: MicroGas 7650 Transcutaneous Monitor

Indications For Use:

The Linde Transcutaneous Monitor is intended to measure the partial pressure of oxygen and carbon dioxide that passes through the cutaneous layer of the skin of an infant who is not under gas anesthesia by a sensor attached to the surface of the infant's skin.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003943

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)